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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-13OE]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Cytology Workload Assessment and Measure – New – Office of Surveillance, Epidemiology and Laboratory (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC provides technical guidance to the Department of Health and Human Services (HHS) in coordination with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) for the implementation of the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Amendments of 1988 directed the Secretary of Health and Human Services to establish the maximum number of cytology slides that any individual may screen in a 24 hour period; to establish certain quality assurance standards; to set personnel standards; and to provide for periodic proficiency testing of cytotechnologists and pathologists involved in screening and interpreting cytological preparations. The

regulations implementing CLIA, published in the *Federal Register* of February 28, 1992, established that the maximum number of slides examined by an individual in each 24 hour period was not to exceed 100 slides and could not be examined in less than an eight-hour day. The regulation further established that the technical supervisor is required to evaluate the performance of cytotechnologists at least every six months and determine their individual maximum daily workload limit. CDC requests OMB approval to collect information on cytology workload practice assessment through a survey on workflow and performance practices of cytotechnologists. Clearance is being requested for one year.

In 1992, when the regulation was published, all Pap slides were conventional "Pap smears." In a conventional Pap smear, samples are smeared directly onto a glass microscope slide after collection. The cells are often obscured by blood or the smear may be too thick and contain contaminating artifacts. Today, almost all Pap tests in the U.S. are collected with a liquid-based method. Instead of "smearing" cervical cells directly onto a glass microscope slide, the cells are sent to the laboratory in a liquid preservative and processed by an automated processor. This processor disperses a uniform thickness representative sample on the slide that is free of obscuring

blood, mucus, and non-diagnostic debris in a circle that covers less than one half of the slide.

The Federal Advisory Committee for CLIA, the Clinical Laboratory Improvement Advisory Committee (CLIAC) has discussed cytology workload on numerous occasions from 1996 until present. The first workgroup was convened in July 1999 to provide input on how to determine workload for liquid-based Pap slides. The workgroup suggested it would be impossible to select one number that would be appropriate for all technology since automated and semi-automated screening devices were in development and approval by FDA might occur in the near future. In 2003, the CLIA requirements were amended to require the manufacturer of a semi-automated screening device to include a maximum workload number in the product insert, rather than set a number in the CLIA regulations.

The same year the amended regulations were made final, the first semi-automated device was approved which further reduced the area of screening by the cytotechnologist by using an automated review microscope to present the cytotechnologist with a set number of fields of view (FOV). This further complicated workload counting since it should take less time to review the FOVS than it would take to manually review the entire circle of the liquid-based preparation. Currently, two systems are FDA-approved, the Hologic ThinPrep® Imaging System and Becton

Dickinson's Focal Point ™ Guided Screening System. The product insert for both devices includes a method of counting slides where slides screened on the automated review microscope will be counted as half (0.5) and a full manual review of the entire circle will be counted as one (1) slide.

CMS and FDA conducted an investigation into problems reported by surveyors of cytology laboratories regarding the two FDA-approved semi-automated screening devices. The investigation led to a different method for calculation of workload than the methods reported in the product inserts. This information was presented at the September 2010 CLIAC meeting and FDA issued an alert - *How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices.* In this alert, it stated laboratories should have a clear standard operation procedure documenting the method of workload counting and explaining how the Technical Supervisor should establish workload limits for each individual. Also, the alert clarified how workload should be calculated when using either the Hologic's ThinPrep® Imaging System or Becton Dickinson's Focal Point ™ Guided Screening System:

- All slides with full manual review (FMR) count as 1 slide (as mandated by CLIA's requirements for manual screening)
- All slides with only field of view (FOV) review count as 0.5 or ½ slide

- Then, slides with both FOV and FMR count as 1.5 or 1 ½ slides
- Use these values to count workload, which should not exceed the CLIA maximum limit of 100 slides in no less than an 8-hour day.

On August 29, 2011 the American Society of Cytopathology's (ASC) Executive Board approved an ASC task force recommendation that the average laboratory cytotechnologist productivity should not exceed 70 slides and that an individual's screening time should not exceed seven (7) hours in a 24 hour period. This recommendation was presented at the ASC 2011 annual meeting and was endorsed unanimously by the Cytology Education and Technology Consortium member organizations: American Society for Clinical Pathology, American Society for Cytotechnology, American Society of Cytopathology, and Papanicolaou Society of Cytopathology. The College of American Pathologists also acknowledged that the current workload limits for image assisted screening devices may be set too high for the average cytotechnologist, but that further study was needed to define best practices for semi-automated gynecologic workload limits. The ASC Taskforce recommendation was presented at the February 2012 CLIAC meeting along with presentations describing workload

studies and use of the workload limit as a target. The committee issued a recommendation that CLIAC supports the use of data from operational studies, such as those presented to CLIAC, to determine if the maximum workload limit using semi-automated screening instruments is appropriate and to discourage the use of regulatory maximum workload limits as productivity targets. CLIAC recommended that standardized criteria be developed for use in determining workload limits for each individual performing screening.

Due to ongoing concerns regarding the appropriateness of the regulatory 100-slide maximum workload limit and lack of a standardized method for counting slides using the semi-automated screening devices, a study is needed to directly assess actual practice. The study needs to include a survey of laboratory practices related to setting individual workload limits. The survey will include questions regarding the maximum workload number of slides for each cytotechnologist employed in the cytology laboratory and how the slides are counted for workload purposes. Since the technical supervisor is required by CLIA to reevaluate the maximum workload number for each individual every six months and to determine policies for workflow and performance practices reporting this information, it is anticipated that the survey may be completed in 30 minutes.

The results of this practice assessment will be used by DLSS/CDC to assist in the development of protocols for a time measurement study to determine the actual time spent screening slides. The results of this practice assessment and the time measure study may be used by HHS agencies responsible for CLIA to determine appropriate gynecologic screening workload maximums using semi-automated devices.

Each laboratory will receive an advance request to participate in the survey from a DLSS contractor that has been selected to collect the survey data and conduct the time measure study. Respondents will be from the 1,245 cytology laboratories in the Unites States. Since a response to this survey is voluntary, we would expect an 80% response rate or approximately 996 laboratories. Responses would be submitted using an electronic web-based interface or in written format. The estimated burden per response is thirty minutes.

CDC expects that information collection will begin in November 2013 and end February 2014.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Cytology laboratories	Cytology Workload Assessment	996	1	30/60	498
				Total	498

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